



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2020-D-1386]

Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled "Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Given the public health emergency presented by COVID-19, this guidance document is being implemented without prior public comment because FDA has determined that prior public participation is not feasible or appropriate, but it remains subject to comment in accordance with the Agency's good guidance practices. The guidance communicates the Agency's intention to exercise enforcement discretion, in the manner described in the guidance, regarding sales to qualified end-users when determining eligibility for the qualified exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, due to disruptions to supply chains, for the duration of the COVID-19 public health emergency.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-D-1386 for "Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover

sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr. (HFS-607), College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr. (HFS-607), College Park, MD 20740, 240-402-1636.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." This policy relates to the supply chain disruptions caused by the public health emergency related to COVID-19, as declared by the Department of Health and Human Services.

Given this public health emergency, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

This guidance document concerns flexibility for the eligibility criteria for the qualified exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (part 112 (21 CFR part 112)) due to disruptions to supply chains due to COVID-19. A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if during the previous 3-year period preceding the applicable calendar year, the average annual monetary value of food the farm sold directly to qualified end-users exceeded the average annual monetary value of the food the farm sold to all other buyers during that period, and the average annual monetary value of all food the farm sold during the 3-year period was less than \$500,000, adjusted for inflation. In order to provide flexibility to affected farms during the COVID-19 public health emergency, under the circumstances described in the guidance FDA does not intend to enforce the criteria regarding the portion of sales that are made to qualified end-users in 2020 (and any subsequent years that are affected by the COVID-19 public health emergency). Specifically, for farms that either met the criteria for the qualified exemption in

2020 based on sales that were made in 2017 to 2019, or that did not have 3 years of sales prior to 2020, but that met the relevant requirements during the years they were in operation prior to 2020, FDA does not intend to enforce the criteria regarding the portion of sales that are made to qualified end-users in years that are affected by the COVID-19 public health emergency. This guidance does not affect the status of farms who continue to sell a majority of their food to qualified end-users despite COVID-19 supply chain disruptions.

This guidance is being issued consistent with FDA's good guidance practices regulation § 10.115(g)(2). The guidance represents the current thinking of FDA on “Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in part 112 have been approved under OMB control number 0910-0816.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: May 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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